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(54) Bioabsorbable interference bone fixation screw

Bioabsorbierbare Interferenzschraube

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(73) Proprietor: **LINVATEC CORPORATION**
Largo, Florida 34643 (US)

(72) Inventors:
- **Ross, Randall D**
  205; Largo Florida 34641 (US)
- **Bassetti, Kevin J**
  Florida 34644 (US)

(74) Representative:
Thomas, Roger Tamlyn
D. Young & Co.
21 New Fetter Lane
London EC4A 1DA (GB)

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Description

BACKGROUND OF THE INVENTION

Field Of The Invention

The present invention relates to surgical screws for fixation in bone and, more specifically, to bioabsorbable interference bone screws particularly useful in securing a ligament in a bone tunnel.

Description Of The Prior Art

Graft and prosthetic ligaments are utilized to surgically repair and/or replace ligaments damaged by injury or disease. Surgical procedures to repair and/or replace ligaments generally involve forming a tunnel in bone, positioning a graft or prosthetic ligament in the bone tunnel, and anchoring the ends, or bone blocks, of the ligament to the walls of the bone tunnel. Various devices are typically employed to secure the bone blocks of the ligament in the bone tunnel, including buttons, staples, expanding cones, unicortical screw posts, as well as interference screws. When interference screws are used, the screws are inserted into the bone tunnel to engage the tunnel wall and the bone blocks of the ligament and, thus, provide an endosteum or endosteal fixation therebetween.

Surgical bone screws for fixation in bone and for anchoring ligaments to bone are typically fabricated from medically approved metallic materials that are not naturally absorbed by the body. An illustrative metallic bone screw is the M. Kurosaka™ bone screw manufactured by DePuy, a division of Boehringer Mannheim Corporation, and a further example of a metallic bone screw is shown in U.S. Patent No. 4,754,749 to Tsou. Most metallic bone screws include a threaded shank joined to an enlarged head having a transverse slot or hexagonal socket formed therein to engage, respectively, a similarly configured, single blade or hexagonal rotatable driver for turning the screw into a bone. The enlarged heads on such screws can protrude from the bone and can cause chronic irritation and inflammation of surrounding body tissue. Metallic bone screws that do not have enlarged heads possess disadvantages because mismatch between screw length and the length of the ligament bone block can result in the screw being inserted too far, or not being inserted to its full length, in the bone tunnel. In anterior cruciate ligament repair and reconstruction, insertion of the screw too far can produce intraarticular penetration, and failure to insert the screw its full length can irritate adjacent soft tissue. Additionally, placement of screws in bone tunnels formed in movable joints can, in certain instances, cause abrading of ligaments during normal motion of the joint. Furthermore, bone screws occasionally back out after insertion; and, when this occurs, the bone screw can protrude into surrounding tissue and cause discomfort. Because metallic bone screws are not assimilated by the body, additional surgical procedures may be required to remove problematic bone screws once the fixated bone and/or tissue has healed.

Biodegradable bone screws have been proposed, as exemplified in US Patent 4,950,270 to Bowman et al, U.S. Patent No. 4,356,572 to Guillemin and International Application PCT/EP 89/00344, and as alluded to in U.S. Patent No. 4,927,421 to Goble et al. Bioabsorbable bone screws possess the advantage of being naturally degradable by the body; and, therefore, contact with surrounding tissue after insertion does not necessitate surgical intervention because the screw will be completely absorbed by the body once the bone and/or tissue has healed. However, conventional bioabsorbable bone screws present numerous difficulties due to bioabsorbable materials being considerably softer than metallic compositions. In particular, bone screws made from bioabsorbable materials are susceptible to deformation and deflection when subjected to forces required to drive the screw into relatively hard tissue, such as bone, and the transverse slot and hexagonal socket typically provided in bone screws as drive recesses for receiving standard, similarly configured, rotatable drivers are unsuitable for bone screws fabricated of bioabsorbable material. The high torque that must be applied to bone screws by a driver to produce rotation of the screw in bone can cause shear deformation of the relatively soft bioabsorbable material, and the surfaces of the drive recesses can be sheared, or stripped, by the drivers. Additionally, single blade and hexagonal drivers tend to force the walls of the drive recesses outwardly when rotated therein producing outward expansion, or "mushrooming" of bioabsorbable screws. Furthermore, some drive recesses extend the entire length of the bone screw, and these drive recesses require that a significant quantity of material be removed from the bone screw resulting in a reduction in strength of the bone screw and impairing the overall resistance of the screw to deformation and damage when being driven into bone. For similar reasons, bioabsorbable bone screws are generally limited to use in open surgery, as opposed to closed, or endoscopic, surgery, because it is advantageous in endoscopic techniques for the screws to be cannulated, i.e. include a central longitudinal bore, for insertion along a guide wire. Formation of the central bore involves removing additional quantities of material from the screw and, therefore, structurally weakens bioabsorbable screws.

Alternative drive recesses, such as those defining multiple, radially oriented prongs for receiving similarly configured, multi-pronged drivers have been proposed for metallic screws, and illustrative drive arrangements are shown in U.S. Patent Nos. 4,084,478 to Simmons; 3,872,904 to Barlow; 3,658,105 to Burt el al; 3,575,080 to Henney; 3,122,963 to Borgeson; 2,445,978 to Stellin; 2,445,525 to Gulden and 2,397,216 to Stellin. These drive recesses are formed in

enlarged heads on metallic industrial screws, and typically taper longitudinally to a narrow end for engaging a similarly tapered driver. Multi-pronged drive recesses designed for metallic screws generally cannot be employed successfully in bioabsorbable bone screws because the forces applied by compatible multi-pronged drivers to such drive recesses include outwardly directed force components that cause outward expansion, or "mushrooming", in bioabsorbable bone screws. Furthermore, the walls defining multi-pronged drive recesses are typically configured to permit outward expansion of the screw material separating the radial prongs of the drive recess when the associated driver imposes force on the walls. Although this configuration is acceptable for metallic screws, it further promotes "mushrooming" in bioabsorbable bone screws due to the inherent relative softness of bioabsorbable materials. Conventional multi-pronged drivers also produce shear on the walls of corresponding drive recesses; and, when utilized in bioabsorbable bone screws, the walls can be sheared off, or stripped, by the drivers. Furthermore, many conventional multi-pronged drive recesses have only a small quantity of screw material separating the radial prongs of the drive recesses, and bioabsorbable bone screws having these types of drive recesses are particularly vulnerable to shear deformation and can not withstand high drive forces. Additionally, the longitudinal taper in conventional multi-pronged drive recesses results in high concentrations of drive forces being applied by the drivers at the narrow end of the drive recesses where there is relatively less screw material to resist deformation, and bioabsorbable screws having tapered drive recesses are likely to experience significant deformation when driven into bone.

SUMMARY OF THE INVENTION

According to one aspect of the invention, there is provided an interference bone fixation screw to be rotated by a driver comprising

a body having a proximal end, a distal end and a longitudinal axis;
a thread means disposed on said body to extend longitudinally therealong; and
drive recess means disposed in said proximal end of said body for receiving rotational forces from the driver,
said interference bone fixation screw being made of bioabsorbable material in its entirety;
characterised in that said drive recess means include a plurality of equally spaced lobe openings having force receiving surfaces in radial alignment with said longitudinal axis, said force receiving surfaces extending longitudinally within said body along a substantial portion of its length.

According to another aspect of the invention, there is provided an interference bone fixation screw in combination with a driver for rotating the screw comprising

a cylindrical body having a proximal end, a distal end and a longitudinal axis;
thread means disposed on said body for engaging bone;
drive recess means in said proximal end of said body for matingly receiving said driver;
said interference bone fixation screw being fabricated entirely of bioabsorbable material; and
a driver including shaft means for being received in said drive recess means;
characterised in that said drive recess means includes a cylindrical cavity disposed concentrically in said body and a plurality of lobe openings disposed around said cavity in communication therewith, each of said lobe openings being defined by force receiving walls extending radially outwardly from said cavity, said force receiving walls extending longitudinally within said body along a substantial portion of its length; and in that said driver includes a plurality of lobe means having force transmitting walls extending radially outwardly from said shaft means for applying forces to said force receiving walls when said driver is rotated.

Certain preferred features are set out in the dependent claims.
Aims of the preferred forms of the invention include:-

(a) to overcome the above mentioned disadvantages associated with prior art metal and bioabsorbable bone screws;
(b) to eliminate radial deformation in the bioabsorbable bone screw when it is driven into bone;
(c) to eliminate shear deformation in the bioabsorbable bone screw when it is driven into bone;
(d) to prevent outward expansion, or "mushrooming", of the bioabsorbable bone screw when it is driven into bone; and
(e) to provide a bioabsorbable bone screw capable of withstanding high drive forces when driven into bone.

Some of the advantages of the preferred bioabsorbable interference bone fixation screw according to the present invention over the prior art are that the bone screw is naturally degraded and absorbed by the body upon completion of healing of the fixated bone and/or tissue, presents no exterior enlargements that might protrude into bodily tissue, is

self-tapping and is suitable for use in closed, or endoscopic, surgery as well as in open surgery.

The preferred bioabsorbable interference bone fixation screw of the present invention comprises a body having a proximal end, a conically tapered distal end and a helical screw thread disposed on the body from the proximal end to the distal end and having a major diameter that defines the major diameter for the bone screw. A drive recess for engaging a rotatable driver is formed in the body to extend longitudinally from the proximal end toward the distal end. The drive recess includes a cylindrical cavity disposed concentrically in the body, and a plurality of lobe openings positioned radially around the cavity in communication therewith and extending longitudinally therealong. Each of the lobe openings is defined by a pair of side walls in radial alignment with the central longitudinal axis of the body, and an arcuate outer wall joining the side walls, such that the lobe openings are wider at the arcuate outer walls and narrower at the cylindrical cavity. A central longitudinal guide bore is formed in the body to extend longitudinally from the drive recess to the distal end for guiding the screw on a guide wire. A driver configured to be matingly received in the drive recess includes a shaft and a plurality of lobes having side walls extending radially outwardly from the shaft for applying concentric forces to the side walls of the drive recess in a direction perpendicular to such side walls.

A preferred embodiment of the invention will now be described by way of example with reference to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side view of the bioabsorbable interference bone fixation screw according to the present invention.
Fig. 2 is a proximal end view of the bioabsorbable interference bone fixation screw of Fig. 1.
Fig. 3 is a perspective view of a driver for rotating the bioabsorbable interference bone fixation screw of Fig. 1.
Fig. 4 is a cross-sectional view of the driver taken along line 6-6 of Fig. 3.
Fig. 5 is a broken, longitudinal sectional view of the driver inserted in the bone screw of Fig. 1.
Fig. 6 is a broken, sectional view showing the bone screw of Fig. 1 being driven by the driver.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Figs. 1 and 2, the bone screw 10 according to the present invention includes a longitudinally elongated cylindrical body 12 having a proximal end 14, a distal end 16 and a helical screw thread 18 disposed externally on body 12 from proximal end 14 to distal end 16. Thread 18 includes a proximal thread section 20 extending longitudinally from the proximal end 14 in the direction of the distal end 16 and a conically tapered distal thread section 24 extending longitudinally from the proximal thread section 20 to the distal end 16. The threads of proximal thread section 20 are of uniform pitch and like-handed; that is, they extend in the same angular direction about the screw. The major diameter (i.e., the diameter of the crests) of the threads in proximal thread section 20 defines the major diameter for the screw, and a cylindrical surface 22 on body 12 defines the minor diameter for proximal thread section 20. Distal thread section 24 carries a thread having a major diameter that is less than the major diameter of the threads in proximal thread section 20. The thread for distal thread section 24 tapers conically from the proximal thread section 20 to the distal end 16 in a spiral configuration, and the pitch of this thread is greater than the pitch of the threads in the proximal thread section 20.

A drive recess 30 for receiving a rotatable driver is formed in body 12 to extend longitudinally from proximal end 14 in the direction of distal end 16 to an end wall 32 disposed perpendicular to the central longitudinal axis of body 12. As best shown in Fig. 2, drive recess 30 includes a cylindrical cavity 34 formed concentrically in body 12 to extend longitudinally from proximal end 14 to end wall 32 and three equally spaced lobe openings or chambers 36 radially disposed around cavity 34 in communication therewith and extending longitudinally therealong to end wall 32. Cavity 34 is defined by three inner arcuate walls 38 positioned between lobe openings 36 and disposed a constant radial distance from the central longitudinal axis of body 12. Each lobe opening 36 is defined by a pair of spaced, planar side walls 40 and an outer arcuate wall 42 joining opposing side walls 40. Outer arcuate walls 42 are disposed a constant radial distance from the central longitudinal axis of body 12, and this radial distance is greater than the radial distance for inner arcuate walls 38. Side walls 40 extend radially outwardly from inner arcuate walls 38 and are positioned in radial alignment with the central longitudinal axis of body 12, such that lobe openings 36 taper inwardly from an outer end 44 defined by outer arcuate walls 42 to a mouth or inner end 46 communicating with cavity 34. Outer arcuate walls 42 are joined to end wall 32 by inwardly curved walls 48, such that the cross-section of drive recess 30 is constant through a substantial portion of its length. A central, longitudinal guide bore or cannulation 50 is disposed concentrically within body 12 in communication with drive recess 30 and extends longitudinally from end wall 32 to distal end 16.

Preferably, the minor diameter for the proximal thread section 20 defined by the surface 22 is 55% to 75% the major diameter for the screw; the thread 18 is configured in accordance with ISO 5835/1; the length of the drive recess 30 from proximal end 14 to end wall 32 is approximately 48% to 95% the overall length of body 12 measured from proximal end 14 to distal end 16; the inner arcuate walls 38 of the cavity 34 define arcs of a circle having a diameter that is approximately 47% the minor diameter of the proximal thread section 20; the outer arcuate walls 42 of the lobe openings 36 define arcs subtending approximately 50° along a circle having a diameter that is approximately 78% the minor

diameter of proximal thread section 20 and these arcs are shorter in length than the arcs defined by inner arcuate walls 38.

The relative proportions of the bone screw produce numerous structural and functional advantages. The relatively large minor diameter for the thread 18 in the proximal thread section 20 increases the quantity of screw material surrounding the drive recess 30 and, therefore, the strength of the bone screw in resisting shear and radial deformation when being rotated by a driver received in the drive recess. The size of the minor diameter for the proximal thread section 20 relative to the major diameter for the bone screw increases the overall strength of the body 12 yet provides thread 18 with sufficient depth to ensure proper fixation in bone. The conical taper for the distal thread section 24 and the spiral configuration and relatively greater pitch of the thread in the distal thread section assists advancement of the bone screw and eliminates the need for a tapping procedure. The length of the drive recess 30 relative to the overall length of the body 12 and to the minor diameter for the proximal thread section 20 allows drive forces to be distributed through body 12 and increases the magnitude of force that the bone screw can withstand. Furthermore, the length of the drive recess 30 is selected to limit the quantity of material removed from the screw and maintain structural integrity around the cannulation 76. Additionally, drive recess 30 distributes drive forces equally throughout its length due to the cross-section of the drive recess being constant through a substantial portion of its length. The diameters of the circles defined by the inner arcuate walls 38 and the outer arcuate walls 42 of the drive recess 30 further insure that a quantity of screw material sufficient to withstand drive forces surrounds the drive recess 30, and the length of the arcs defined by the outer arcuate walls 42 provides relatively large quantities of screw material between the lobe openings 36.

Bone screw 10 is fabricated entirely from a bioabsorbable or biodegradable polymer or copolymer having an absorption or degradation time selected in accordance with the anticipated healing time for the fixated tissue. Table I set forth below lists polymers (and copolymers and terpolymers thereof) suitable for bone screw 10, and these polymers are all biodegradable into water-soluble, non-toxic materials that are safely eliminated by the body. Although the illustrative polymers are normally linear, suitable cross linked resins can be prepared therefrom.

TABLE I

Polymer
Polycaprolactone
Poly (L - lactide)
Poly (DL - lactide)
Polyglycolide
95:5 Poly (DL - lactide - co-glycolide)
90:10 Poly (DL - lactide - co-glycolide)
85:15 Poly (DL - lactide - co-glycolide)
75:25 Poly (DL - lactide - co-glycolide)
50:50 Poly (DL - lactide - co-glycolide)
90:10 Poly (DL - lactide - co-caprolactone)
75:25 Poly (DL - lactide - co-caprolactone)
50:50 Poly (DL - lactide - co-caprolactone)

A preferred material for bone screw 10 is Poly (L-Lactide), and the preferred chemical specifications for raw polylactide acid employed for bone screw 10 are set forth below in Table II.

TABLE II

Raw Poly-Lactic Acid
Residual Tin (Stannous octoate): Less than 200ppm
Residual Metals (FE, Cr, Ni, Pb): Less than 50ppm each
Residual Lactide Dimer: Less than 1%
Intrinsic Viscosity: 6.5 - 8.5 $\frac{dl}{g}$ in chloroform at 25°C

Bone screw 10 is preferably formed by an injection molding process, and the preferred characteristics of the bone screw thusly formed are set forth below in Table III.

TABLE III

Bone Screw
Ultimate Tensile Strength: 62055 - 103425 kPA (9,000 - 15,000 psi)
Tensile Modulus: 2275350 - 3654350 kPa (330,000 - 530,000 psi)
Maximum Bending Strength: 88945.5 - 144105.5 kPA (12,900 - 20,900 psi)
Bending Modulus: 2875215 - 4254215 kPa (417,000 - 617,000 psi)
Intrinsic Viscosity: 2.0-4.5 $\frac{dl}{g}$ in chloroform at 25°C

A rotatable driver 60 for engagement in drive recess 30 is shown in Figs. 3 and 4 and includes a longitudinally elongated, cylindrical shaft 62 having a proximal end 64 joined to a handle 66, a distal end 68 defining a distal end wall 70 disposed perpendicular to the central longitudinal axis of shaft 62, and three lobes 72 disposed radially on shaft 62 to extend longitudinally from proximal end 64 to distal end 68. Lobes 72 each include spaced, planar side walls 74 extending radially outwardly with respect to the central longitudinal axis of shaft 62 and an outer arcuate wall 76 joining side walls 74, such that side walls 74 are closer together at shaft 62 and farther apart at outer arcuate wall 76. Outer arcuate walls 76 are joined to distal end wall 70 by inwardly curved walls 78, such that the cross-sections of lobes 72 and shaft 62 are constant through a substantial portion of their length. A longitudinal guide bore 80 is formed concentrically in shaft 62 and handle 66 to extend the entire length of shaft 62 and handle 66. As shown in Figs. 5 and 6, shaft 62 is sized to be matingly received in cavity 34 of drive recess 30 and lobes 72 are sized to be matingly received in lobe openings 36 of drive recess 30.

In operation, bone screw 10 can be employed in ligament repair and/or reconstruction surgery to attach a bone block on a ligament to the wall of a bone tunnel. For example, for ligament fixation in endoscopic intraarticular replacement of the anterior cruciate ligament of the knee, appropriate portals are made leading to the knee joint for insertion of an arthroscope and other instruments, and bone tunnels are formed, respectively, in the proximal tibia and distal femur. A ligament, either graft or prosthetic, having bone blocks at its ends is passed through the femoral tunnel, across the joint, and through the tibial tunnel to position a bone block in the femoral and tibial tunnels. Sutures carried by the bone blocks permit the ligament to be placed in tension. Bone screw 10 is inserted via guide bore 50 over a guide wire positioned in the femoral bone tunnel between the bone block positioned therein and the tunnel wall. Driver 60 is placed over the guide wire via guide bore 80 and is guided into mating engagement with drive recess 30 as shown in Fig. 5. Driver 60 is rotated to drive bone screw 10 into interference fit between the bone block and the wall of the femoral bone tunnel. With the ligament held in tension, a second bone screw 10 is inserted to secure the remaining bone block with respect to the wall of the tibial bone tunnel.

As shown in Fig. 6, when driver 60 is rotated, the leading radial side walls 74 of lobes 72 apply radial forces equally against corresponding radial side walls 40 of lobe openings 36, and these rotational forces are concentric to the central longitudinal axis of body 12. The forces applied by side walls 74 to side walls 40 are directed perpendicularly, and not outwardly, against side walls 40. Therefore, forces are applied by driver 60 only in the direction needed to drive screw 10, and extraneous forces that would otherwise produce distortion or outward expansion of screw 10 are eliminated. Because lobe openings 36 taper inwardly from outer ends 44 to mouths 46, the screw material separating lobe openings 36 is restricted, or confined, against outward expansion when the leading side walls 74 of driver 60 are forced

against corresponding side walls 40.

Claims

1. An interference bone fixation screw (10) to be rotated by a driver comprising

   a body (12) having a proximal end (14), a distal end (16) and a longitudinal axis;
   a thread means (18) disposed on said body (12) to extend longitudinally therealong; and
   drive recess means (30) disposed in said proximal end (14) of said body (12) for receiving rotational forces from the driver,
   said interference bone fixation screw (10) being made of bioabsorbable material in its entirety;
   characterised in that said drive recess means include a plurality of equally spaced lobe openings (36) having force receiving surfaces (40) in radial alignment with said longitudinal axis, said force receiving surfaces (40) extending longitudinally within said body (12) along a substantial portion of its length.

2. An interference bone fixation screw as recited in claim 1 wherein said lobe openings (36) have outer ends (42) disposed a first radial distance from said longitudinal axis and inner ends (46) disposed a second radial distance from said longitudinal axis less than said first radial distance, said lobe openings (36) tapering inwardly from said outer ends to said inner ends to define planar force receiving walls (40) between said outer ends and said inner ends for receiving concentric rotational forces from the driver applied perpendicular to said walls (40).

3. An interference bone fixation screw as recited in claim 2 wherein said drive recess means (30) includes a cylindrical cavity (34) disposed concentrically in said proximal end (14) of said body (12) and said inner ends of said lobe openings (36) communicate with said cylindrical cavity (34).

4. An interference bone fixation screw as recited in claim 3 wherein said cylindrical cavity (34) is defined by a plurality of inner arcuate walls (38) positioned, respectively, between said inner ends of said lobe openings (36).

5. An interference bone fixation screw as recited in claim 4 wherein said outer ends of said lobe openings are defined by outer arcuate walls (42) joining said force receiving walls (40).

6. An interference bone fixation screw as recited in claim 5 wherein said outer arcuate walls (42) define arcs of a circle, said inner arcuate walls (38) define arcs of a circle and said arcs defined by said inner arcuate walls are longer than said arcs defined by said outer arcuate walls.

7. An interference bone fixation screw as recited in claim 6 wherein said thread means (18) defines a major diameter and said body (12) defines a minor diameter extending longitudinally from said proximal end toward said distal end.

8. An interference bone fixation screw as recited in claim 7 wherein the diameter of said circle defined by said outer arcuate walls (42) is about 78 % said minor diameter.

9. An interference bone fixation screw as recited in claim 7 or 8 wherein the diameter of said circle defined by said inner arcuate walls (38) is about 47% said minor diameter.

10. An interference bone fixation screw as recited in any one of claims 6-9 wherein said arcs defined by said outer arcuate walls (42) subtend about 50°.

11. An interference bond fixation screw as recited in any one of claims 3-10 further including a longitudinal guide bore (50) disposed concentrically in said body (12) to extend longitudinally from said cavity (34) to said distal end (16).

12. An interference bone fixation screw as recited in claim 11 further including an end wall (32) disposed in said body perpendicular to said longitudinal axis, said drive recess means (30) extending longitudinally in said body (12) from said proximal end (14) to said end wall (32).

13. An interference bone fixation screw as recited in any preceding claim wherein said thread means (18) includes a helical screw thread (20).

14. An interference bone fixation screw as recited in claim 13 wherein said helical screw thread (20) defines a major diameter and said body (12) defines a minor diameter along said helical screw thread.

15. An interference bone fixation screw as recited in claim 14 wherein said minor diameter is 55% to 75% said major diameter.

16. An interference bone fixation screw as recited in claim 13, 14 or 15 wherein said helical screw thread (20) is of uniform pitch.

17. An interference bone fixation screw as recited in claim 13, 14, 15 or 16 wherein said thread means (18) further includes a spiral screw thread (24) extending longitudinally from said helical screw thread (20) to said distal end (16).

18. An interference bone fixation screw as recited in claim 17 wherein said spiral screw thread (24) has a pitch and said spiral screw thread pitch is greater than said helical screw thread pitch.

19. An interference bone fixation screw as recited in any preceding claim wherein said body is cylindrical.

20. An interference bone fixation screw as recited in any preceding claim wherein said thread means is disposed on said body from said proximal end to said distal end.

21. An interference bone fixation screw as recited in any preceding claim wherein said interference bone fixation screw is made entirely of Poly (L-Lactide).

22. An interference bone fixation screw as recited in any preceding claim wherein there are three of said lobe openings (36).

23. An interference bone fixation screw as recited in any preceding claim wherein the cross-section of said drive recess means (30) is constant through a substantial portion of the longitudinal length of said drive recess means.

24. An interference bone fixation screw as recited in any preceding claim wherein the longitudinal length of said drive recess means (30) is 48% to 95% the length of said body (12) from said proximal end (14) to said distal end (16).

25. An interference bone fixation screw (10) in combination with a driver (60) for rotating the screw comprising

a cylindrical body (12) having a proximal end (14), a distal end (16) and a longitudinal axis;
thread means (18) disposed on said body (12) for engaging bone;
drive recess means (30) in said proximal end (14) of said body for matingly receiving said driver (60);
said interference bone fixation screw (10) being fabricated entirely of bioabsorbable material; and
a driver (60) including shaft means (62) for being received in said drive recess means (30);
characterised in that said drive recess means includes a cylindrical cavity (34) disposed concentrically in said body (12) and a plurality of lobe openings (36) disposed around said cavity (34) in communication therewith, each of said lobe openings (36) being defined by force receiving walls (40) extending radially outwardly from said cavity (34), said force receiving walls (40) extending longitudinally within said body (12) along a substantial portion of its length; and in that said driver includes a plurality of lobe means (72) having force transmitting walls (74) extending radially outwardly from said shaft means (62) for applying forces to said force receiving walls (40) when said driver (60) is rotated.

26. An interference bone fixation screw and driver as recited in claim 25 including an end wall (32) disposed in said body (12) perpendicular to said longitudinal axis, said drive recess means (30) extending longitudinally from said proximal end (14) to said end wall (32).

27. An interference bone fixation screw and driver as recited in claim 26 wherein said shaft means (62) includes an end surface (70) disposed perpendicular to the longitudinal axis of said shaft means for engaging said end wall (32).

Patentansprüche

1. Interferenz-Knochenbefestigungsschraube (10) zur Drehung mit Hilfe eines Schraubenziehers mit

einem Körper (12) mit einem proximalen Ende (14), einem distalen Ende (16) und einer Längsachse,

einem Gewinde (18), das auf dem Körper (12) angeordnet ist und sich ihm entlang in Längsrichtung erstreckt,

und

einer Antriebsvertiefung (30), die in dem proximalen Ende (14) des Körpers (12) zur Aufnahme von Rotationskräften von dem Schraubenzieher angeordnet ist,

wobei die Interferenz-Knochenbefestigungsschraube (10) in ihrer Gesamtheit aus biologisch absorbierbarem Material besteht,
dadurch gekennzeichnet, daß die Antriebsvertiefung mehrere in gleichem Abstand angeordnete Lappenöffnungen (36) mit kraftaufnehmenden Oberflächen (40) in radialer Ausrichtung mit der Längsachse enthält, wobei sich die kraftaufnehmenden Oberflächen (40) in Längsrichtung in dem Körper (12) entlang einem wesentlichen Teil seiner Länge erstrecken.

2. Interferenz-Knochenbefestigungsschraube nach Anspruch 1, bei der die Lappenöffnungen (36) in einem ersten radialen Abstand von der Längsachse angeordnete Außenenden (42) und in einem zweiten radialen Abstand von der Längsachse, der geringer als der erste radiale Abstand ist, angeordnete Innenenden (46) haben, wobei sich die Lappenöffnungen (36) von den Außenden zu den Innenenden nach innen verjüngen und ebene kraftaufnehmende Wände (40) zwischen diesen Außenenden und den Innenenden begrenzen, um konzentrische Drehkräfte von dem Schraubenzieher aufzunehmen, die senkrecht zu den Wänden (40) ausgeübt werden.

3. Interferenz-Knochenbefestigungsschraube nach Anspruch 2, bei der die Antriebsvertiefung (30) einen zylindrischen Hohlraum (34) enthält, der konzentrisch in dem proximalen Ende (14) des Körpers (12) angeordnet ist, und die Innenenden der Lappenöffnungen (36) in Verbindung mit dem zylindrischen Hohlraum (34) stehen.

4. Interferenz-Knochenbefestigungsschraube nach Anspruch 3, bei der der zylindrische Hohlraum (34) durch mehrere innere gekrümmte Wände (38) begrenzt ist, die jeweils zwischen den Innenenden der Lappenöffnungen (36) positioniert sind.

5. Interferenz-Knochenbefestigungsschraube nach Anspruch 4, bei der die Außenenden der Lappenöffnungen durch äußere gekrümmte Wände (42) begrenzt sind, welche die kraftaufnehmenden Wände (40) verbinden.

6. Interferenz-Knochenbefestigungsschraube nach Anspruch 5, bei der die äußeren gekrümmten Wände (42) Bögen eines Kreises definieren, die inneren gekrümmten Wände (38) Bögen eines Kreises definieren und die durch die inneren gekrümmten Wände definierten Bögen länger als die durch die äußeren gekrümmten Wände definierten Bögen sind.

7. Interferenz-Knochenbefestigungsschraube nach Anspruch 6, bei der das Gewinde (18) einen größeren Durchmesser begrenzt und der Körper (12) einen kleineren Durchmesser begrenzt, der sich in Längsrichtung von dem proximalen Ende zu dem distalen Ende erstreckt.

8. Interferenz-Knochenbefestigungsschraube nach Anspruch 7, bei der der Durchmesser des von den äußeren gekrümmten Wänden (42) begrenzten Kreises etwa 78 % des kleineren Durchmessers ist.

9. Interferenz-Knochenbefestigungsschraube nach Anspruch 7 oder 8, bei der der Durchmesser des durch die inneren gekrümmten Wände (38) begrenzten Kreises etwa 47 % des kleineren Durchmessers ist.

10. Interferenz-Knochenbefestigungsschraube nach einem der Ansprüche 6 bis 9, bei der die durch die äußeren gekrümmten Wände (42) definierten Bögen etwa 50° begrenzen.

11. Interferenz-Knochenbefestigungsschraube nach einem der Ansprüche 3 bis 10, weiterhin mit einer konzentrisch in dem Körper (12) in Längsrichtung angeordneten Führungsbohrung (50), die sich von dem Hohlraum (34) zu dem distalen Ende (16) in Längsrichtung erstreckt.

12. Interferenz-Knochenbefestigungsschraube nach Anspruch 11 weiterhin mit einer in dem Körper senkrecht zu der Längsachse angeordneten Endwand (32), wobei sich die Antriebsvertiefung (30) in Längsrichtung in dem Körper (12) von dem proximalen Ende (14) zu der Endwand (32) erstreckt.

13. Interferenz-Knochenbefestigungsschraube nach einem der vorausgehenden Ansprüche, bei der das Gewinde (18) ein spiralförmiges Schraubengewinde (20) einschließt.

14. Interferenz-Knochenbefestigungsschraube nach Anspruch 13, bei der das spiralförmige Schraubengewinde (20) einen größeren Durchmesser begrenzt und der Körper (12) einen kleineren Durchmesser entlang dem spiralförmigen Schraubengewinde begrenzt.

15. Interferenz-Knochenbefestigungsschraube nach Anspruch 14, bei der der kleinere Durchmesser 55 bis 75 % des größeren Durchmessers ist.

16. Interferenz-Knochenbefestigungsschraube nach Anspruch 13, 14 oder 15, bei der das spiralförmige Schraubengewinde (20) eine gleichmäßige Steigung hat.

17. Interferenz-Knochenbefestigungsschraube nach Anspruch 13, 14, 15 oder 16, bei der das Gewinde (18) weiterhin ein spiralförmiges Schraubgewinde (24) einschließt, das sich in Längsrichtung von dem spiralförmigen Schraubengewinde (20) zu dem distalen Ende (16) erstreckt.

18. Interferenz-Knochenbefestigungsschraube nach Anspruch 17, bei der das spiralförmige Schraubengewinde (24) eine Steigung hat und die Steigung dieses spiralförmigen Schraubengewindes größer als die Steigung des anderen spiralförmigen Schraubengewindes ist.

19. Interferenz-Knochenbefestigungsschraube nach einem dervorausgehenden Ansprüche, bei der der Körper zylindrisch ist.

20. Interferenz-Knochenbefestigungsschraube nach einem der vorausgehenden Ansprüche, bei der das Gewinde auf dem Körper von dem proximalen Ende bis zu dem distalen Ende angeordnet ist.

21. Interferenz-Knochenbefestigungsschraube nach einem dervorausgehenden Ansprüche, bei der die Interferenz-Knochenbefestigungsschraube vollständig aus Poly-(L-lactid) besteht.

22. Interferenz-Knochenbefestigungsschraube nach einem dervorausgehenden Ansprüche, bei der drei der Lappenöffnungen (36) vorhanden sind.

23. Interferenz-Knochenbefestigungsschraube nach einem der vorausgehenden Ansprüche, bei der der Querschnitt der Antriebsvertiefung (30) über einen wesentlichen Teil der Länge der Antriebsvertiefung in Längsrichtung konstant ist.

24. Interferenz-Knochenbefestigungsschraube nach einem dervorausgehenden Ansprüche, bei der die Länge der Antriebsvertiefung (30) in Längsrichtung 48 bis 95 % der Länge des Körpers (12) von dem proximalen Ende (14) bis zu dem distalen Ende (16) ist.

25. Interferenz-Knochenbefestigungsschraube (10) in Kombination mit einem Schraubenzieher (6) zur Drehung der Schraube mit einem zylindrischen Körper (12) mit einem proximalen Ende (14), einem distalen Ende (16) und einer Längsachse,

einem Gewinde (18), das auf dem Körper (12) im Eingriff mit dem Knochen angeordnet ist,

einer Antriebsvertiefung (30) in dem proximalen Ende (14) des Körpers zur passenden Aufnahme des Schraubenziehers (69),

wobei die Interferenz-Knochenbefestigungsschraube (10) in ihrer Gesamtheit aus biologisch absorbierbarem Material besteht, und

einem Schraubenzieher (60), der einen Schaft (62) zur Aufnahme in der Antriebsvertiefung (30) einschließt, **dadurch gekennzeichnet**, daß die Antriebsvertiefung einen konzentrisch in dem Körper (12) angeordneten zylindrischen Hohlraum (34) und mehrere um den Hohlraum (34) in Verbindung mit ihm angeordnete Lappenöffnungen (36) einschließt, wobei jede dieser Lappenöffnungen (36) durch kraftaufnehmende Wände (40) begrenzt ist, die sich von dem Hohlraum (34) aus radial nach außen erstrecken, und sich die kraftaufnehmenden Wände (40) in Längsrichtung in dem Körper (12) über einen wesentlichen Teil seiner Länge erstrecken, und daß der Schraubenzieher mehrere Lappen (72) mit kraftübertragenden Wänden (74) enthält, die sich von dem Schaft (62) aus radial nach außen erstrecken, um Kräfte auf die kraftaufnehmenden Wände (40) auszuüben, wenn der Schraubenzieher (60) gedreht wird.

26. Interferenz-Knochenbefestigungsschraube und Schraubenzieher nach Anspruch 25 mit einer in dem Körper (12) senkrecht zu der Längsachse angeordneten Endwand (32), wobei sich die Antriebsvertiefung (30) in Längsrichtung von dem proximalen Ende (14) zu dieser Endwand (32) erstreckt.

27. Interferenz-Knochenbefestigungsschraube und Schraubenzieher nach Anspruch 26, bei denen der Schaft (62) eine senkrecht zu der Längsachse des Schaftes zur Anlage an der Endwand (32) angeordnete Endfläche (70) aufweist.

Revendications

1. Vis à interférence de fixation osseuse (10) destinée à être tournée par un tournevis comprenant :

   un corps (12) comportant une extrémité proximale (14), une extrémité distale (16) et un axe longitudinal ;
   un moyen de filet (18) disposé sur ledit corps (12) pour s'étendre longitudinalement le long de celui-ci ; et
   un moyen d'évidement d'entraînement (30) disposé dans ladite extrémité proximale (14) dudit corps (12) pour recevoir des forces de rotation depuis le tournevis,
   ladite vis de fixation osseuse à interférence (10) étant faite de matériau bioabsorbable dans son intégralité ;
   caractérisée en ce que ledit moyen d'évidement d'entraînement comprend une pluralité d'ouvertures de lobes équidistantes (36) comportant des surfaces de réception de forces (40) en alignement radial avec ledit axe longitudinal, lesdites surfaces de réception de forces (40) s'étendant longitudinalement au sein dudit corps (12) le long d'une partie substantielle de sa longueur.

2. Vis de fixation osseuse à interférence selon la revendication 1, dans laquelle lesdites ouvertures de lobes (36) comportent des extrémités externes (42) disposées à une première distance radiale dudit axe longitudinal et des extrémités internes (46) disposées à une seconde distance radiale dudit axe longitudinal inférieure à ladite première distance radiale, lesdites ouvertures de lobes (36) allant en diminuant vers l'intérieur desdites extrémités externes auxdites extrémités internes afin de définir des parois de réception de forces planes (40) entre lesdites extrémités externes et lesdites extrémités internes destinées à recevoir des forces de rotation concentriques du tournevis appliquées perpendiculairement auxdites parois (40).

3. Vis de fixation osseuse à interférence selon la revendication 2, dans laquelle ledit moyen d'évidement d'entraînement (30) comprend une cavité cylindrique (34) disposée concentriquement dans ladite extrémité proximale (14) dudit corps (12) et lesdites extrémités internes desdites ouvertures de lobes (36) communiquent avec ladite cavité cylindrique (34).

4. Vis de fixation osseuse à interférence selon la revendication 3, dans laquelle ladite cavité cylindrique (34) est définie par une pluralité de parois arquées internes (38) positionnées, respectivement, entre lesdites extrémités internes desdites ouvertures de lobes (36).

5. Vis de fixation osseuse à interférence selon la revendication 4, dans laquelle lesdites extrémités externes desdites ouvertures de lobes sont définies par des parois arquées externes (42) reliant lesdites parois de réception de forces (40).

6. Vis de fixation osseuse à interférence selon la revendication 5, dans laquelle lesdites parois arquées externes (42) définissent des arcs de cercle, lesdites parois arquées internes (38) définissent des arcs de cercle et lesdits arcs définis par lesdites parois arquées internes sont plus longs que lesdits arcs définis par lesdites parois arquées externes.

7. Vis de fixation osseuse à interférence selon la revendication 6, dans laquelle ledit moyen de filet (18) définit un diamètre extérieur et ledit corps (12) définit un diamètre intérieur s'étendant longitudinalement de ladite extrémité proximale vers ladite extrémité distale.

8. Vis de fixation osseuse à interférence selon la revendication 7, dans laquelle le diamètre dudit cercle défini par lesdites parois arquées externes (42) est d'environ 78 % dudit diamètre intérieur.

9. Vis de fixation osseuse à interférence selon la revendication 7 ou 8, dans laquelle le diamètre dudit cercle défini par lesdites parois arquées internes (38) est d'environ 47 % dudit diamètre intérieur.

10. Vis de fixation osseuse à interférence selon l'une quelconque des revendications 6 à 9, dans laquelle lesdits arcs

définis par lesdites parois arquées externes (42) sous-tendent environ 50°.

11. Vis de fixation osseuse à interférence selon l'une quelconque des revendications 3 à 10, comprenant, en outre, un alésage de guidage longitudinal (50) disposé concentriquement dans ledit corps (12) pour s'étendre longitudinalement de ladite cavité (34) à ladite extrémité distale (16).

12. Vis de fixation osseuse à interférence selon la revendication 11, comprenant, en outre, une paroi d'extrémité (32) disposée dans ledit corps perpendiculairement audit axe longitudinal, ledit moyen d'évidement d'entraînement (30) s'étendant longitudinalement dans ledit corps (12) de ladite extrémité proximale (14) à ladite paroi d'extrémité (32).

13. Vis de fixation osseuse à interférence selon l'une quelconque des revendications précédentes, dans laquelle ledit moyen de filet (18) comprend un filet de vis hélicoïdal (20).

14. Vis de fixation osseuse à interférence selon la revendication 13, dans laquelle ledit filet de vis hélicoïdal (20) définit un diamètre extérieur et ledit corps (12) définit un diamètre intérieur le long dudit filet de vis hélicoïdal.

15. Vis de fixation osseuse à interférence selon la revendication 14, dans laquelle ledit diamètre intérieur est de 55 % à 75 % dudit diamètre extérieur.

16. Vis de fixation osseuse à interférence selon la revendication 13, 14 ou 15, dans laquelle ledit filet de vis hélicoïdal (20) a un pas uniforme.

17. Vis de fixation osseuse à interférence selon la revendication 13, 14, 15 ou 16, dans laquelle ledit moyen de filet (18) comprend, en outre, un filet de vis en spirale (24) s'étendant longitudinalement dudit filet de vis hélicoïdal (20) à ladite extrémité distale (16).

18. Vis de fixation osseuse à interférence selon la revendication 17, dans laquelle ledit filet de vis en spirale (24) a un pas et ledit pas du filet de vis en spirale est supérieur audit pas du filet de vis hélicoïdal.

19. Vis de fixation osseuse à interférence selon l'une quelconque des revendications précédentes, dans laquelle ledit corps est cylindrique.

20. Vis de fixation osseuse à interférence selon l'une quelconque des revendications précédentes, dans laquelle ledit moyen de filet est disposé sur ledit corps de ladite extrémité proximale à ladite extrémité distale.

21. Vis de fixation osseuse à interférence selon l'une quelconque des revendications précédentes, dans laquelle ladite vis de fixation osseuse à interférence est entièrement faite de Poly (L-Lactide).

22. Vis de fixation osseuse à interférence selon l'une quelconque des revendications précédentes, dans laquelle lesdites ouvertures de lobes (36) sont au nombre de trois.

23. Vis de fixation osseuse à interférence selon l'une quelconque des revendications précédentes, dans laquelle la section transversale dudit moyen d'évidement d'entraînement (30) est constante sur une portion substantielle de la longueur longitudinale dudit moyen d'évidement d'entraînement.

24. Vis de fixation osseuse à interférence selon l'une quelconque des revendications précédentes, dans laquelle la longueur longitudinale dudit moyen d'évidement d'entraînement (30) est de 48 % à 95 % de la longueur dudit corps (12) de ladite extrémité proximale (14) à ladite extrémité distale (16).

25. Vis de fixation osseuse à interférence (10) combinée avec un tournevis (60) pour faire tourner la vis, comprenant :

un corps cylindrique (12) comportant une extrémité proximale (14), une extrémité distale (16) et un axe longitudinal ;
un moyen de filet (18) disposé sur ledit corps (12) pour engager l'os ;
un moyen d'évidement d'entraînement (30) dans ladite extrémité proximale (14) dudit corps pour recevoir par engagement ledit tournevis (60) ;
ladite vis de fixation osseuse à interférence (10) étant entièrement faite de matériau bioabsorbable ; et
un tournevis (60) comprenant un moyen d'arbre (62) destiné à être reçu dans ledit moyen d'évidement d'entraînement (30) ;

caractérisée en ce que ledit moyen d'évidement d'entraînement comprend une cavité cylindrique (34) disposée concentriquement dans ledit corps (12) et une pluralité d'ouvertures de lobes (36) disposées autour de ladite cavité (34) en communication avec elle, chacune desdites ouvertures de lobes (36) étant définie par des parois de réception de forces (40) s'étendant radialement vers l'extérieur de ladite cavité (34), lesdites parois de réception de forces (40) s'étendant longitudinalement au sein dudit corps (12) le long d'une partie substantielle de sa longueur ; et en ce que ledit tournevis comprend une pluralité de moyens de lobes (72) comportant des parois de transmission de forces (74) s'étendant radialement vers l'extérieur dudit moyen d'arbre (62) pour appliquer des forces sur lesdites parois de réception de forces (40) lorsque ledit tournevis (60) est entraîné en rotation.

26. Vis de fixation osseuse à interférence et tournevis selon la revendication 25, comprenant une paroi d'extrémité (32) disposée dans ledit corps (12) perpendiculairement audit axe longitudinal, ledit moyen d'évidement d'entraînement (30) s'étendant longitudinalement de ladite extrémité proximale (14) à ladite paroi d'extrémité (32).

27. Vis de fixation osseuse à interférence et tournevis selon la revendication 26, dans laquelle ledit moyen d'arbre (62) comprend une surface d'extrémité (70) disposée perpendiculairement audit axe longitudinal dudit moyen d'arbre pour engager ladite paroi d'extrémité (32).

FIG. 1

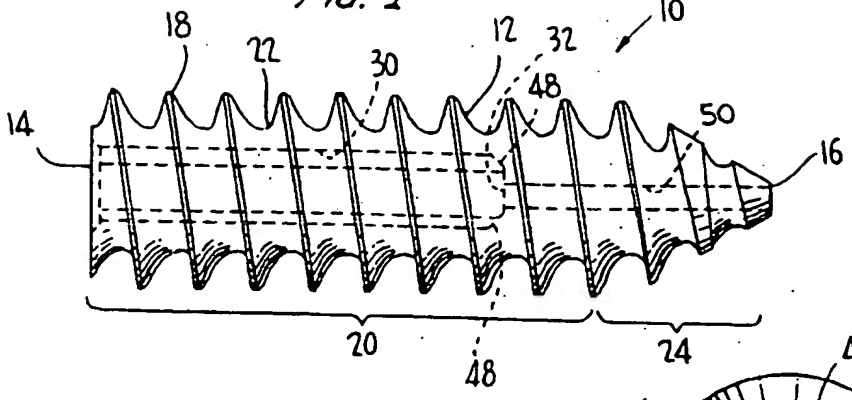

FIG. 2

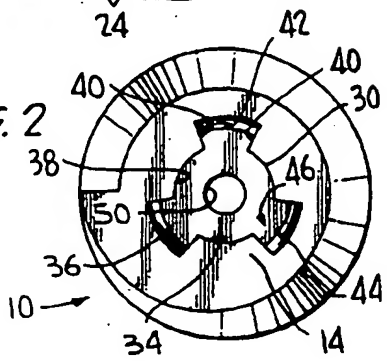

FIG. 5

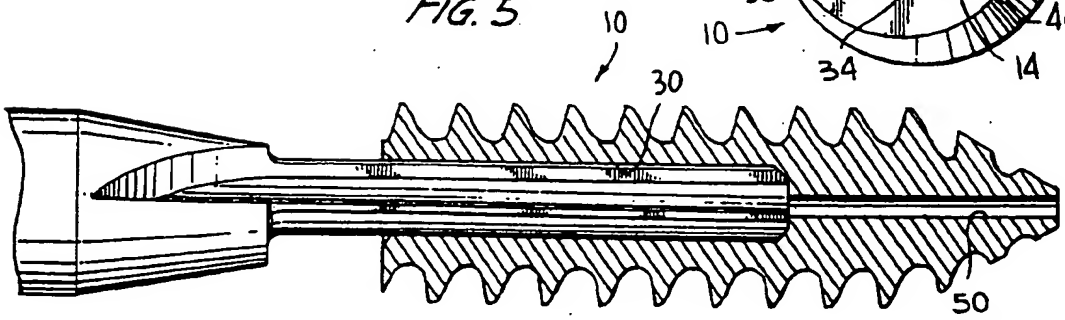

FIG. 3

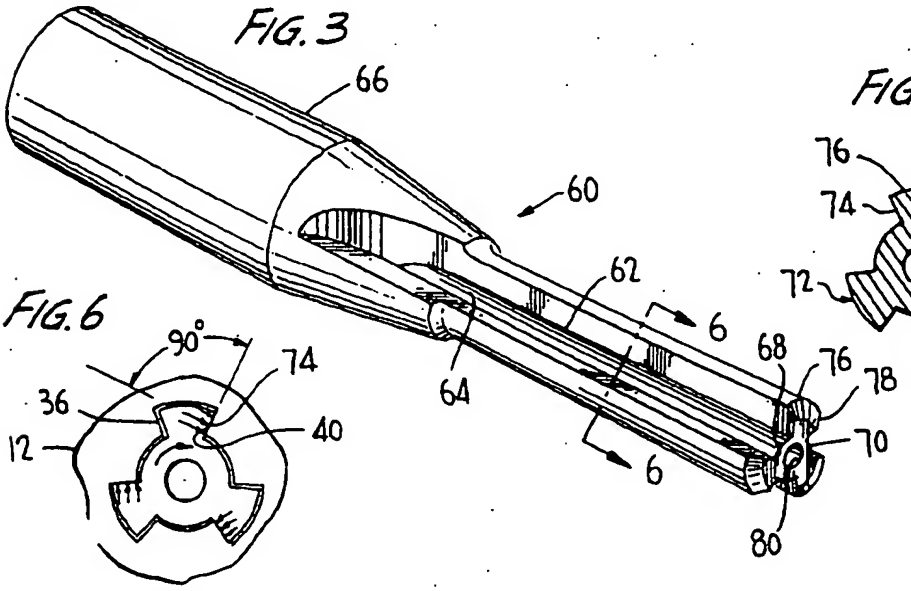

FIG. 4

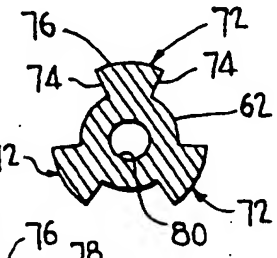

FIG. 6